REMARKS

The office action of March 9, 2005 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 3 through 7, 8 through 11, 15 through 18, and 21 through 28 remain in this case, claims 2, 7, 13 through 14, and 20 being cancelled, claims 26-28 being added and claims 3 through 6, 8 through 11, 16 through 18, 21, and 23 through 25 being amended by this response. No new matter has been added. More specifically, claims 26-28 are fully supported by page 3, lines 26-28 and Figure 3 of the application, as filed.

The Applicant would like to respectfully point out that the European Patent Office recently allowed the corresponding European case, with similar adjusting means language as is found in one or more of the claims of the present application.

Objection to the Specification

The specification was objected to because the Examiner states that the Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention in claim 10. The Examiner further states that the Applicant is required to amend the specification to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element.

The Examiner does not specifically point out the language in claim 10 that he believes needs to be added to the specification. To further prosecution of the application, the Applicant will try to respond to this objection. The Applicant respectfully requests, however, that if the Examiner repeats this objection in a subsequent office action, that he clarify the language in claim 10 that he is specifically requiring to be added to the specification.

In addition, the Applicant respectfully points out that the Applicant already responded to the Examiner's objection that the specification did not provide proper antecedent basis for claim 10 in the Applicant's last office action response, which is what is required in M.P.E.P. 608.01(o).

M.P.E.P 608.01(o) states:

"The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term.

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted.

New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, Ex parte Kotler, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01.

The specification should be objected to if it does not provide proper antecedent basis for the claims by using form paragraph 7.44."

Claim 10, includes, in part, "means for providing individual patient parameters and/or aerosol parameters for the inhalation". The specification specifically discusses examples of these means. Examples of these means are clearly described in the specification on page 3, lines 6 through 25, and therefore, the Applicant should not be required to add any description to the disclosure regarding this part of claim 10.

Claim 10 also includes, in part, "adjusting means for adjusting individual aerosol doses on the basis of the predetermined individual patient parameters and/or aerosol parameters by adjusting a respiratory flow and/or a tidal volume of the inhalation device, wherein the adjusting means for adjusting the individual aerosol doses reads out the individual patient

parameters and/or aerosol parameters for the inhalation from the means for providing individual patient parameters and/or aerosol parameters for the inhalation, evaluates them and, on the basis thereof, adjusts the respiratory flow and the tidal volume of the inhalation device."

The specification specifically discusses adjusting the dosage on page 2, line 30 to page 3, line 5. In addition, valve control is specifically disclosed in the application (present application, page 3, lines 26-34, more specifically lines 27-28, "Thus, the individual patient and/or aerosol parameters influence the individual dosage of the aerosol/s either manually or automatically (e.g. via a respective valve control)."). In addition, Figure 3 is a diagram showing the adjustment of flow rates for an individual patient.

Although support for the claim language can also be found on page 2, line 30 to page 3, line 5, page 3, lines 26-32, page 5, lines 12-14, claim 10, as originally filed, and in the Abstract on page 9, lines 7-10, the Applicant has added a paragraph to the specification to define the adjusting means of claim 10. No new matter has been added. Specifically, the language in the added paragraph is fully supported by claims 10 and 18, as well as page 3, lines 26-34 of the application, as filed.

Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Objection to the Claims

Claims 2-11 were objected to because the Examiner states that Applicant has evoked sixth paragraph, means plus function language to define Applicant's invention. As discussed above, the objection to the specification should be overcome. Therefore, the objection to the claims should also be overcome. Reconsideration and withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. §112

Claims 2-11, 13-18 and 20-25 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Applicant respectfully disagrees with this rejection.

The test for enablement is put forth in M.P.E.P. 2164.01. "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)." (emphasis added).

As far as the Applicant knows, the present invention was the first to introduce individualized inhalation. A much more optimized inhalation of an aerosol is obtainable if the

respiratory flow and the tidal volume (and the size of the particles) are individually selected for the specific patient. Such parameters are obtained, for example, by a physician or a health care institution and are in practice stored on a memory medium such as a smart card. The smart card is given to the patient who inserts the smart card, for example at home, into the inhalation device. The inhalation device then controls inhalation of the patient on the basis of these individual parameters. To help the Examiner understand the invention, the Applicant respectfully encloses a brochure describing in detail the product AKITA that is based on the invention claimed in the present application. The inhalation with this system is described on page 6 of the brochure as follows:

"The AKITA can be individually adjusted for each patient on the basis of a lung function test. The patient's optimized breathing pattern is stored on a smart card, which, similar to a phone card, is slid into the AKITA device before the first inhalation. In this way, we at Inamed program an individual breathing pattern on the smart card for the respective medication and for the individual patient's lung function. This ensures an optimum treatment for every patient and every drug. The AKITA can even be set up so that the aerosol will be delivered to certain lung regions. If the lung function parameters or drug dosage change, we simply exchange the smart card."

Thus, with the inventive inhalation device, controlled inhalation is provided with high accuracy: the drug indeed reaches the target area in the lung. Such a controlled and targeted inhalation has not been achieved in the art prior to the applicant's invention.

Those skilled in the art would know that the adjustment of the respiratory flow and the tidal volume can be made, in practice, by valves or by controlling the air pump of the inhalator. Once a person skilled in the art understands the concept of inhalation on the basis of individual parameters (measured or obtained beforehand), the person skilled in the art would be able to put this concept into practice.

Regarding claims 10 and 18, someone skilled in the art would be able to practice the invention without undue experimentation. Those skilled in the art know that there are many ways to adjust respiratory flow and tidal volume (including valves, controlling the air pump of an inhalator, or providing a controller/software for the inhalation device in order to provide the correct control signals to the mechanical components of the inhalator), and would be able to use

that knowledge to practice the invention in claims 10 and 18. One example, valves, is even mentioned in the application on page 3, line 28. Practicing the invention of claims 10 and 18 would not require one skilled in the art to perform any experimentation, let alone undue experimentation.

Claims 3-6, 8-9, 11 and 15-17, being dependent upon and further limiting claims 10 and 18, respectively, should also be allowable for that reason, as well as for the additional recitations they contain.

Regarding claim 25, the Examiner states that "[t]he means for adjusting and the adjustment mechanism claimed in the above claims has not been disclosed in such a way that one skilled in the art would have been able to make and use the device. It is unclear what structure would be capable of performing the claimed functions and exactly how it would interact or interconnect with the other explicitly claimed elements of the invention to arrive at the specified functions." (present office action dated March 9, 2005, page 3, lines 12-16). Claim 25 is a method claim, and does not include an adjusting means of an adjusting mechanism.

Claim 25 includes, in part, the step of "adjusting individual aerosol doses administered by the device on the basis of the predetermined individual patient parameters and/or aerosol parameters by adjusting a respiratory flow and/or a tidal volume of the inhalation device, wherein the step of adjusting includes evaluating the individual patient parameters and/or aerosol parameters for the inhalation and, on the basis thereof, adjusting respiratory flow and title volume of the inhalation device".

Those skilled in the art know would be able to adjust individual aerosol doses administered by the inhalation device, because it is well known in the art that there are many ways to adjust respiratory flow and tidal volume (including valves or controlling the air pump of an inhalator).

Claims 21-24, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 2-11, 13-18 and 25 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner states that one skilled in the art would not be able to identify the structure which makes up the claimed adjusting means or adjustment mechanism, thus making the scope of the claim unclear and indefinite. Applicant respectfully disagrees with this rejection.

Regarding claims 10 and 18, those skilled in the art would be able to identify a structure making up the adjusting means or the adjusting mechanism. As discussed above with respect to the enablement requirement, adjusting respiratory volumes and tidal flow are well known in the art, and there are many ways of making these adjustments. Claims 3-6, 8-9, 11 and 15-17, being dependent upon and further limiting claims 10 and 18, respectively, should also be allowable for that reason, as well as for the additional recitations they contain.

Regarding claim 25, this claim does not include the language "adjusting means" or "adjusting mechanism" that the Examiner states renders the claims indefinite. Therefore, the rejection of claim 25 is improper. Claims 21-24, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. §102

Claims 10, 2-4, 7, 8, 11, 18, 13-15, 25 and 20-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Goodman (5,813,397). Applicant respectfully disagrees with the rejection.

Goodman does not disclose an inhalation apparatus that provides a targeted inhalation. For example, column 5, lines 51 to 59 states that it is an object to provide for varying the dosage or controlled amount of the aerosolised compound delivered for inspiration by the patient in response to detected changes in the patient's pulmonary function during a course of therapy directed to improving pulmonary function. Thus, this prior art reference considers only a single patient, and is particularly focused on changes that result from the therapy.

The prior art, including Goodman, does not disclose the present invention, where an inhalation is started from individualized parameters so that inhalation is exactly tailored to the needs of a specific patient.

Amended claim 10 includes, "means for providing individual patient parameters and/or aerosol parameters for the inhalation comprising a memory medium, wherein the individual patient parameters and/or aerosol parameters are stored on the memory medium before the inhalation". The amendment is fully supported by claims 2 and 7, as filed. The Examiner states that Goodman discloses a system of a ventilator which provides doses of an aerosol according to a patient specific protocol or regimen. However, Goodman et al. does not disclose providing individual patient parameters and/or aerosol parameters for inhalation comprising a memory medium, wherein the individual patient parameters and/or aerosol parameters are stored on the memory medium before the inhalation.

Claim 10 also includes, "adjusting means for adjusting individual aerosol doses on the basis of the predetermined individual patient parameters and/or aerosol parameters by adjusting a respiratory flow and/or a tidal volume of the inhalation device, wherein the adjusting means for adjusting the individual aerosol doses reads out the individual patient parameters and/or aerosol parameters for the inhalation from the means for providing individual patient parameters and/or aerosol parameters for the inhalation, evaluates them and, on the basis thereof, adjusts the respiratory flow and the tidal volume of the inhalation device". Goodman does not provide an adjusting means for adjusting individual aerosol does on the basis of predetermined individual patient parameters and/or aerosol parameters. Goodman also does not disclose a means for reading those parameters, evaluating them, and adjusting respiratory flow and tidal volume accordingly.

The Examiner points to the following passages to support his statement that claim 10 is disclosed in Goodman.

> "Microprocessor 2000 is provided with suitable software programming that controls the operation of the device. Optionally, electronics 3400 may include a voltage converter and an associated output port for converting the digital information to a voltage format compatible for communicating with another microprocessor device, for example,

an RS232 port or a facsimile machine (not shown). Further, as discussed in detail below, electronics 3400 may include means for reading a canister code for identifying the contents of the medication to be administered and selecting the device administration protocol for the identified medication (not shown)." (Col. 21, lines 30-42)

This passage merely discloses a microprocessor. The microprocessor does not provide individual patient parameters and/or aerosol parameters for inhalation. In addition, it is not a memory medium that individual patient parameters and/or aerosol parameters are stored on before the inhalation. Although the microprocessor is capable of identifying the contents of the medication to be administered, it does not read and evaluate individual patient parameters and/or aerosol parameters for inhalation.

"In another alternate embodiment of the present invention, the software is programmed to measure pulmonary function periodically, preferably prior to each administration of a dosage, and look for changes in the detected flow patterns and measured pulmonary functions of the patient during the course of treatment. Those detected changes are then used to modify the treatment parameters in accordance with the improved or degenerated condition of the patient. For example, the dosage per administration and the frequency of administration could be adjusted as indicated by detected changes in the patient's condition. Similarly the dosage could be adjusted from administration to administration by measuring the time between administration to determine a maximum allowed dosage based on accepted medical practices." (Col. 31, lines 15-29).

In this embodiment, the software measures pulmonary function, and modifies treatment accordingly. This modification is based on changes in a single patient. The system does not provide individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters and/or aerosol parameters are stored on a memory medium before inhalation. The system does not read and evaluate individual patient parameters and/or aerosol parameters for inhalation.

In another alternate embodiment of the present invention, each canister 3200 is provided with a code that identifies the contents of the canister, and system electronics 3400 includes means (not shown) for reading a code associated with canister 3200. In one

such embodiment, the code is entered externally and in another such embodiment the code is provided automatically when canister 3200 is inserted into base 3100. The code may be read each time canister 3200 is inserted into base 3100 and used by microprocessor 2000 to customize the software programming for delivery of the particular medication. In one embodiment, the code is in the form of product labeling, e.g., a universal bar code, and a code sensor for reading a printed universal bar code (not shown) comprises a photodetector array and a light emitting diode to provide illumination for the photodetector array to read the bar code. Preferably, the bar code is of the circular form so that it can be read regardless of the orientation of canister 3200 in base 3100. In another embodiment, the code may be a digital word integral with the canister and a code sensor for reading the digital word could include electrodes in the base for engaging the code that are connected to the microprocessor. If necessary, the changes in the software for delivery of a particular drug that cannot be provided by a code scheme could be installed in microprocessor 2000 software at the time the device and medication are given to the patient. Alternately, the microprocessor could be configured to request the information from an external source when the code provided is not in the library of selected medications. This programming may be performed by changing the EEPROM or its contents by providing appropriate instructions to microprocessor 2000 or its associated memory through a conventional external communications port.

Preferably, the code also identifies the application for that medication in circumstances where the medication is useful for more than one application or may be used in conjunction with more than one carrier composition having different affinities for deposition. Thus, the code will provide information concerning dosage amounts and times and will provide the information for controlling solenoid 3150 to select an aerosol having a desired particle size distribution for favorable deposition into desired locations in the patient's pulmonary system. This will ensure that the medication is delivered in accordance with its intended delivery characteristics and protocols." (Col. 31, line 30-col. 32, line 7).

In this embodiment, a canister containing the medication includes a code. The code provides information regarding the identity of the medication, as well as dosage amounts and times. The canister and code do not provide individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters

and/or aerosol parameters are stored on a memory medium before inhalation. The system does not read and evaluate individual patient parameters and/or aerosol parameters for inhalation.

> "In accordance with the present invention, valve 3150 is controlled by microprocessor 2000 and is used as a high frequency switch to release a series of pulses of the aerosol medication having a selectable width, shape, and frequency. The pulses are delivered to the patient through nozzle 3160 mouth end 3142 mouthpiece 3110. By selecting the time period and frequency that valve 3150 is open, the pulse width and interval between adjacent pulses can be selected. Having selected for the desired particle size, the patient's breathing pattern can then be used to identify the optimal points or points at which to deliver the pulses of aerosol medication for delivery to the desired locus or loci in the airway. Further, the selected particle size can then be used with an optimal inspiratory flow, inspiratory pause, expiratory flow, and tidal volume to deliver the aerosol medication to the most therapeutically efficacious locations in the patient's airway. It should be understood that each such dose given as a sequence of pulses can be deposited at different loci by changing the delivery schedule with respect to at which point or points in the inspiratory flow the aerosol is delivered for inspiration." (Col. 34, lines 30-46).

This embodiment releases a series of pulses of medication. The patient's breathing pattern is used to identify points to deliver the pulses. This passage does not disclose individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters and/or aerosol parameters are stored on a memory medium before inhalation. The system does not read and evaluate individual patient parametesr and/or aerosol parameters for inhalation.

"In accordance with this alternate embodiment of the invention, another function of microprocessor 2000 is to select an optimum particle size and delivery schedule for the medication to be administered for the patient". (Col. 34, line 66 to col. 35, line 2). This passage does not disclose individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters and/or aerosol parameters are stored on a memory medium before inhalation. The system does not read and evaluate individual patient parameters and/or aerosol parameters for inhalation.

"Other anticipated uses of the present invention could be to provide optimal delivery of drugs in aerosol form, based on measured inspiratory and expiratory flow, such as beta-agonists, e.g., albuterol for bronchial-constriction, inhaled steroids for bronchial inflammation, pentamidine for pneumocystis prophylaxis in patients who have tested positive for HIV, narcotics, e.g., morphine or other opiate derivatives, for patients having chronic pain, allowing for effective self-medication exploiting the rapid onset of an aerosol medication administration technique, and without substantial risk of overdosing, and with providing the medical examiner a record of the drug administration for evaluation in the event of continued therapy." (Col. 35, line 63 to col. 35, line 8).

This passage discloses other uses for Goodman's invention, including providing optimal delivery of drugs in aerosol form. These alternative uses do not disclose patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters and/or aerosol parameters are stored on a memory medium before inhalation. The system does not read and evaluate individual patient parameters and/or aerosol parameters for inhalation.

Therefore, since claim 10 includes one or more elements not disclosed in Goodman, claim 10 is not anticipated by Goodman.

Claims 3-4, 8 and 11, being dependent upon and further limiting claim 10, respectively, should also be allowable for that reason, as well as for the additional recitations they contain.

Amended claim 18 includes, in part, "an input mechanism that supports inputs into the device of individual patient parameters and/or aerosol parameters for the inhalation, wherein the input mechanism comprises a memory medium, wherein the individual patient parameters and/or aerosol parameters for the inhalation are stored by the memory medium before inhalation. The amendment is fully supported by claims 13 and 14, as filed.

Amended claim 18 also includes "an adjustment mechanism that adjusts individual aerosol doses administered by the device on the basis of the predetermined individual patient parameters and/or aerosol parameters by adjusting a respiratory flow and/or a tidal volume of the inhalation device, wherein the adjustment mechanism accesses the individual patient parameters and/or aerosol parameters for the inhalation through the input mechanism;

evaluates them; and, on the basis thereof, adjusts respiratory flow and tidal volume of the inhalation device.

Goodman does not disclose individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, no individual patient parameters and/or aerosol parameters are stored on a memory medium before inhalation. Goodman also does not disclose reading and evaluating individual patient parameters and/or aerosol parameters for inhalation. Therefore, since claim 18 includes one or more elements not disclosed in Goodman, claim 18 is not anticipated by Goodman.

Claims 15-17, being dependent upon and further limiting claim 18, respectively, should also be allowable for that reason, as well as for the additional recitations they contain.

Claim 25 includes the step of "inputting into a device individual patient parameters and/or aerosol parameters for the inhalation comprising the substeps of inserting a memory medium into the device and storing the individual patient parameters and/or aerosol parameters for the inhalation on the memory medium before inhalation". The amendment is fully supported by claims 7, 14 and 20, as filed.

Claims 25 also includes the step of "adjusting individual aerosol doses administered by the device on the basis of the predetermined individual patient parameters and/or aerosol parameters by adjusting a respiratory flow and/or a tidal volume of the inhalation device, wherein the step of adjusting includes evaluating the individual patient parameters and/or aerosol parameters for the inhalation and, on the basis thereof, adjusting respiratory flow and tidal volume of the inhalation device."

Goodman does not disclose inputting individual patient parameters and/or aerosol parameters for the inhalation into a device. Goodman does not disclose inserting a memory medium into the device or storing the individual patient parameters and/or aerosol parameters for the inhalation on the memory medium before inhalation. Goodman also does not disclose adjusting individual aerosol doses administered by the device on the basis of the predetermined individual patient parameters and/or aerosol parameters. In addition, Goodman does not disclose evaluating individual patient parameters and/or aerosol parameters for inhalation and adjusting

respiratory flow and tidal volume accordingly. Therefore, since claim 25 includes one or more elements not disclosed in Goodman, claim 25 is not anticipated by Goodman.

Claims 21-24, being dependent upon and further limiting claim 10, respectively, should also be allowable for that reason, as well as for the additional recitations they contain.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 5, 6, 9, 16, 17, 23 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Wallace (6,024,089). Applicant respectfully disagrees with this rejection. The argument regarding the anticipation of claims 10, 18, and 25 is repeated here by reference.

Wallace et al. relates to a ventilator. Even if Wallace et al. taught manual inputting means, as stated by the Examiner, Wallace does not teach or suggest an inhalation device or method which uses individual parameters storable on a memory medium prior to inhalation in order to provide a controlled and targeted inhalation, as in the present invention.

Regarding claim 10, upon which claims 5, 6, and 9 depend, Goodman does not teach or suggest individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, Goodman does not teach or suggest any individual patient parameters and/or aerosol parameters being stored on a memory medium before inhalation. Goodman also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation. Therefore, claim 10 is not obvious over Goodman.

Wallace does not provide what Goodman lacks. Wallace teaches "a ventilation control system for controlling the ventilation of a patient. The ventilation control system utilizes a user-friendly user interface for the display of patient data and ventilator status, as well as for entering values for ventilation settings to be used to control the ventilator and for setting and displaying appropriate alarms settings and patient data." (Abstract).

Wallace does not teach or suggest any individual patient parameters and/or aerosol parameters being stored on a memory medium before inhalation. Wallace also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 10. Therefore, claim 10 is not obvious over Goodman and Wallace. Claims 5, 6, and 9, being dependent upon and further limiting claim 10, should also be allowable for that reason, as well as for the additional recitations they contain.

Regarding claim 18, upon which claims 16 and 17 depend, Goodman does not teach or suggest individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, Goodman does not teach or suggest any individual patient parameters and/or aerosol parameters being stored on a memory medium before inhalation. Goodman also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation. Therefore, claim 18 is not obvious over Goodman.

Wallace does not provide what Goodman lacks. Wallace teaches "a ventilation control system for controlling the ventilation of a patient. The ventilation control system utilizes a user-friendly user interface for the display of patient data and ventilator status, as well as for entering values for ventilation settings to be used to control the ventilator and for setting and displaying appropriate alarms settings and patient data." (Abstract).

Wallace does not teach or suggest any individual patient parameters and/or aerosol parameters being stored on a memory medium before inhalation. Wallace also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 18. Therefore, claim 18 is not obvious over Goodman and Wallace. Claims 16 and 17, being dependent upon and further limiting claim 18, should also be allowable for that reason, as well as for the additional recitations they contain.

Regarding claim 25, upon which claims 23 and 24 depend, Goodman does not teach or suggest inputting individual patient parameters and/or aerosol parameters for inhalation on a memory medium. In addition, Goodman does not teach or suggest storing any individual patient parameters and/or aerosol parameters on a memory medium before inhalation. Goodman also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation. Therefore, claim 25 is not obvious over Goodman.

Wallace does not provide what Goodman lacks. Wallace teaches "a ventilation control system for controlling the ventilation of a patient. The ventilation control system utilizes a user-friendly user interface for the display of patient data and ventilator status, as well as for entering values for ventilation settings to be used to control the ventilator and for setting and displaying appropriate alarms settings and patient data." (Abstract).

Wallace does not teach or suggest inputting any individual patient parameters and/or aerosol parameters or storing those parameters on a memory medium before inhalation. Wallace also does not teach or suggest reading and evaluating individual patient parameters and/or aerosol parameters for inhalation.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, claim 25 is not obvious over Goodman and Wallace. Claims 5, 23 and 24, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain.

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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